IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Bowman
Application Serial No.: 09/737,185
Filed: 12/14/2000
Confirmation No.: 9139
For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Appeal No. ----
Group No.: 1743

Examiner: Gakh, Yelena G.

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appeal Brief

This Appeal Brief is being transmitted in this application with respect to the Notice of Appeal filed September 29, 2010. A previous Appeal Brief was filed November 17, 2005, with respect to the Notices of Appeal filed on June 28, 2005 and June 12, 2006. The Appeal Brief fee was paid with an earlier brief. Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account 501923.

This brief contains these items under the following headings, and in the order set forth below:

APPELLANT'S BRIEF

1. Real Party in Interest

The real party in interest in this appeal is GBF, Inc.

2. Related Appeals and Interferences

There are no appeals or interferences that will directly affect or be directly affected by, or have a bearing on the Board's decision in this appeal. This application was previously the subject of Appeal no. 2009-2011, which was remanded to the Examiner for further work on April 20, 2009. Appellant chose to reopen prosecution, but the examiner re-sent the case to the Board, where it was assigned Appeal number 2009-014382.

Appellant sought remand for consideration of arguments presented and Appeal number 2009-014382 was dismissed by a paper mailed January 26, 2010.

3. Status of the Claims

Claims 1-21, 38 and 40-44 remain in the case with none of the claims being allowed or allowable. Claims 22-37 and 39 were previously cancelled without prejudice. Claims 1-21, 38, and 40-44 are the subject of this appeal.

4. Status of the Amendments

No amendment was submitted after the final Office Action mailed July 13, 2010.

5. Summary of Claimed Subject Matter

Appellant's claimed invention relates to improvements in identification, logistics control, and information management for biomedical specimens collected for diagnostic or toxicology testing. Diagnostic and toxicology specimens are typically collected for analytical testing from donors at collection sites such as hospitals, clinics, or doctors' offices. These specimens are collected in primary specimen containers specifically designed to completely and safely contain the specimens during handling and shipment in order to preserve the integrity of the specimens and to protect the health of persons who come in contact with the containers. In addition, primary toxicological specimen containers are typically provided with tamperproof locks or seals to ensure that the integrities of the toxicological specimens are not breached by unauthorized persons or by mishandling of the containers. The specimen containers are provided from a vessel distribution facility, that can be a manufacturer, distributor, or warehouse.

Successful testing requires the collection, recording, and maintenance of essential information about each diagnostic or toxicology specimen. Such information includes the identity and nature of each specimen, the identity of the specimen donor, the test or tests to be performed on the specimen, the identity of the person collecting the sample, the time and place of collection, and the results of tests performed on the specimen. Also, toxicology specimens typically require written authorizations signed by their donors. Because most specimen collection sites do not have testing laboratories on site, the specimens are typically sent to remote reference laboratories. Accordingly, the pertinent information about a particular specimen must be accurately communicated to the laboratory which tests the specimen, and the laboratory must in turn accurately report the test results for that specimen back to the site where the specimen was originally collected or to another remote site.

Prior to Appellant's invention the recording, maintenance, and communication of specimen and testing information was usually done using preprinted, duplicate-page forms having spaces for manually entering designated information onto the forms. Duplicate copies of the completed forms were used to communicate and record information among and between multiple departments or sites involved with the handling or testing of a specimen. It was common for such forms to have sequential numbers and bar codes that correspond to matching bar coded labels which could be affixed to the specimen containers corresponding to the written information on the associated forms. These bar codes could be scanned to identify the specimens contained in the bar-coded containers, and the bar codes on the forms could be scanned to correlate the recorded information with the specimen. In addition, written

or typed information often included on labels on the specimen containers showed details about the contained specimens. The primary specimen containers and copies of the associated forms were typically maintained together by placing them together in secondary containers such as boxes or sleeves. These secondary containers are then transported to a reference laboratory to conduct the required tests on the specimens.

Particularly for toxicology specimens such as urine specimens to be tested for illicit drugs, reliable, legal evidence linking the specimen to be tested to the donor is critical.

Because the specimens originate from multiple remote collection sites, the collection and delivery of such specimens requires coordination between the collection sites, the laboratory, and a courier. Because many collection sites have only a sporadic need for diagnostic or toxicology testing, it is often inefficient for a designated courier to visit a potential collection site daily or semi-daily to possibly collect specimens for delivery. In order to avoid such inefficiency, collection sites must typically notify either the laboratory or a courier each time specimens are awaiting collection for delivery to the laboratory, causing a different type of inefficiency.

Reference laboratories have typically included automated handling and testing equipment. Such laboratories have had automated sorters and conveyors for routing specimens to testing stations and testing equipment that automatically performed the required tests on the specimens with minimal manual human intervention. However, even such automated laboratories received and inventoried specimens from remote

specimen collection sites by manually unpacking each specimen and the associated forms from their boxes or sleeves. The laboratories typically used manual bar code scanners to individually scan the bar code labels on the received specimen containers and forms. The data was then manually input into computers that controlled the automated handling and testing equipment. The specimens were manually staged for introduction into the automated systems. Once testing had been performed on a specimen, a laboratory typically recorded the test results manually on the associated forms and then reported the test results by sending the completed forms to the originating specimen collection site or other selected destination.

Those methods for information management and logistical control for biological specimens collected for diagnostic or toxicology testing caused a number of difficulties. The use of written forms and written labels to record, maintain, and communicate specimen information was especially problematic. Manual entry of information onto forms or labels at collection sites and laboratories was labor intensive and caused delays in processing the specimens and information. Also, written forms or labels were sometimes illegible or became obliterated by handling or spills, causing a loss or miscommunication of essential information. Furthermore, it was necessary to physically maintain copies of the forms with the associated specimens. These forms added bulk to transport packaging for the specimen containers, and there was a risk of loss or dissociation from the specimens. In addition, the forms had to be individually handled and scanned or read when received by a reference laboratory, adding labor cost and causing delays, leading to underutilization of the automated laboratory handling and test equipment. Lost or

dissociated forms could cause potentially harmful delays in the testing or reporting of diagnostic test results for distressed donors experiencing medical emergencies. In addition, if a form containing an authorization signature of a toxicology specimen donor was lost or misplaced, the test could not be performed until the donor again authorized the test.

Bar codes did not eliminate the need for written forms to record and manage specimen information nor the associated problems. In addition, the bar codes on specimens and forms still required individual scanning and conveyed only limited basic identity information about the specimens.

Also, because independent specimen collection sites generated specimens only sporadically, the process of collecting specimens from these sites was problematic. Having couriers regularly visit sites having no specimens for collection wasted labor and transportation costs. Alternatively, having the sites request collection on a case-by-case basis was also labor intensive and subject to communication delays or miscommunication.

As claimed in independent Claim 1 and the claims dependent thereon, the present invention provides a diagnostic specimen system for identifying and controlling biomedical or toxicology specimens and managing information associated with the specimens. Diagnostic systems test for disease and the like. Toxicology tests look for toxic substances, including illegal drugs. The system provides a diagnostic or toxicology specimen container having an electronic memory tag for remote, non-contact recording and reading of data stored therein. Other claims are

directed to embodiments of a method of using the system to manage information associated with the specimens.

The diagnostic specimen system includes a population of biomedical specimen collection vessels, such as the vessel 1, shown in Figure 1. Attached to each of the vessels 1 is a wireless electronic memory tag 3 bearing a unique electronic identification code. The tags 3 remain attached to the vessels 1 as each is transported between a vessel distribution facility (such as a vendor's warehouse), a specimen collection facility (such as a doctor's office), and a specimen testing laboratory facility (such as a laboratory), as depicted by the flowchart of Figure 4.

Also, in various embodiments, the memory tags 3 store data representing an identification code for the vessel 1, the identity of the supplier of the vessel 1, and product information about the vessel 1. The data may relate to the specimen donor and may identify the specimen contained in the vessel 1. The data may also define analytical tests to be performed on the specimen. Each vessel 1 may also include an attached label 4 imprinted with an identifying bar code 7. Figures 1 and 5 show these additional optional features of the system.

Claim 9 and its dependents are directed to a toxicology specimen system. Collection vessels 1 are configured to receive and contain a toxicology specimen, and wireless electronic memory tags 3 are attached to the vessels. The wireless tags 3 remain attached to the vessels 1 as they are transported. The tags 3 are for non-contact storage and retrieval of information and contain stored data including an encoded electronic signature of the donor of a toxicology specimen. Claims 10-16 detail several additional features, and claim 17 recites several of those features in

combination. Claim 38 is directed to the toxicology specimen collection vessel, including a tamper-indicating seal.

Additional embodiments of a toxicology specimen system are claimed that include a population of collection vessels 1. Each of the collection vessels 1 is configured to receive and contain a toxicology specimen and has a wireless electronic memory tag 3 attached for non-contact storage and retrieval of information. The memory tag 3 contains stored data including an encoded electronic signature of the donor of a toxicology specimen. The population of collection vessels includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility. Members of the population are transportable between the facilities, and the tag 3 is attached to the vessel 1 such that it remains attached to the vessel 1 as it is transported between facilities.

Claim 18 recites a method for electronically storing information on a diagnostic or toxicology specimen vessel 1 and remotely reading information from the vessel 1. The method includes providing a population of biomedical specimen vessels 1, as shown in Figure 4. Attached to each of the vessels 1 is a wireless electronic memory tag 3. The population of vessels 1 includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility. The method further includes storing data on one of the memory tags 3 at the vessel distribution facility, shipping or distributing population members with the stored data from the distribution facility to the collection facility, and reading the stored information from the electronic memory tag 3 with a non-contact electronic reader or scanner at a specimen testing laboratory

facility. The memory tags 3 remain attached to the vessels during the shipping or distributing.

Claim 19 recites a method involving collecting specimens in the recited vessels and storing information about the specimen and its donor.

Claim 42 recites the population of vessels for collecting toxicology specimens, with some members of the population at the vessel distribution facility, some at a collection facility and some at a testing laboratory. Claim 43 recites a similar population of biomedical specimen collection vessels.

Claim 44 covers either type of specimen collection and details procedures involved in the specimen collection phase.

In an embodiment, the method that is depicted in the flow chart labeled Figure 4 of the application includes collecting a specimen from a donor in the specimen container at the collection facility, and storing information about the specimen, donor, and/or tests to be performed on the specimen on the memory tags 3. The method may also include collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

Use of the invention provides numerous advantages. These include improved reliability in the record handling, since the reliance on human data input is reduced. The shipping cost of the sample-filled vessels is reduced because they no longer need to be packaged with paperwork. The reference laboratory pickup of the vessels is more efficient, since linked computers of the specimen collection facility and specimen testing laboratory facility can be programmed to provide couriers with up-to-date routing information to make stops only at specimen collection facilities where

specimens are ready for pick-up. The laboratory facility can enjoy further efficiency gains from being able to scan an incoming load of specimen vessels almost instantaneously and then be able to schedule the required testing stations, personnel or reagents for the respective tests needed on the specimens in the received load. This, in turn, allows the tests to be completed more quickly, so that the test results can be available more quickly. Perhaps in some medical situations, lives can be saved by this faster turn-around.

In the field of toxicology testing, the all-important chain of custody is made more reliable, since the identity of the specimen donor remains in the database, linked to the adhered wireless electronic memory tag.

The argued claims on appeal are "mapped" to the specification by page and line number or paragraph number and/or drawings as follows:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels (Figure 1, item 1), at least some members of the population being located at a vessel distribution facility (Figure 5, item 27), other members of the population being located at a specimen collection facility (Figure 5, item 28), further members of the population being located at a specimen testing laboratory facility (Figure 5, item 31), and additional members of the population being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag, a unique electronic identification code stored on the electronic memory tag (Figure 1, item 3, page 12, line 19) for non-contact storage and retrieval of

information directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities.

2. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag includes a radio frequency transponder. (page 11, lines 13-15)

3. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including an identification code for the vessel. (page 11, line 22)

4. A diagnostic specimen system as claimed in claim 3 further including a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel. (page 11, line 5)

5. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including the identity of a supplier of the vessel and product information about the vessel. (page 12, line 2)

8. A diagnostic specimen system comprising:

a population of collection vessels, at least some members of the population being located at a vessel distribution facility (Figure 5, item 27), other members of the population being located at a specimen collection facility (Figure 5, item 28), further members of the population being located at a specimen testing laboratory facility (Figure 5, item 31), and additional members being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag(Figure 5), with a unique electronic identification code stored on the electronic memory tag for non-contact storage and retrieval of information directly attached

thereto (page 12, line 19) such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities;

data stored on electronic memory tags of members at the specimen collection facility including an identification code for the vessel to which the tag is directly attached, the identity of the supplier of the vessel (Page 11, line 2) and product information about the vessel (Page 11, line 2), identifying information about a specimen contained in the vessel (Page 11, lines 4-5) and about the specimen donor (Page 11, lines 4-5), and definition of the analytical tests to be performed on the specimen in the vessel (Page 11, lines 5-6); and

a label imprinted with an identifying bar code (Figure 2, item 7) attached to each vessel.

9. A toxicology specimen system comprising

a population of collection vessels (Figure 5, items 27, 28 & 31),

each configured to receive and contain a toxicology specimen and having a

wireless electronic memory tag (Figure 3) directly attached to the

vessel for non-contact storage and retrieval of information,

wherein the population includes members located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory (Figure 5, items 27, 28 & 31),

and additional members being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag, with a unique electronic identification code stored on the electronic memory tag

for non-contact storage and retrieval of information directly attached thereto such (page 12, line 19) that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities (Figure 3).

10. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag includes a radio frequency transponder. (page 11, line 13-15)

11. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including an identification code for the vessel. (page 11, line 22)

12. A toxicology specimen system as claimed in claim 11 further including a label imprinted with an identifying bar code attached to each vessel. (page 11, line 5)

13. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including the identity of the supplier of the vessel and product information about the vessel. (page 12, line 2)

16. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen. (page 13, line 24- page 14, line 2)

17. A toxicology specimen system (Page 2, lines 16-17) comprising:

a population of biomedical specimen collection vessels, wherein the population includes members located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility (Figure 5, items

27, 28 & 31), and additional members of the population being transported between the facilities,

each vessel having a wireless electronic memory tag directly attached to the vessel such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities, the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information (Page 11, lines 13-21);

data stored on the electronic memory tags including an identification code for the vessel that is unique to the tag on the vessel (Figure 4, item 11), the identity of the supplier of the vessel (Page 11, line 2) and product information about the vessel (Page 11, line 2), identifying information about a specimen contained in the vessel and about the specimen donor (Page 11, lines 4-5), definition of the analytical tests to be performed on the specimen in the vessel (Page 11, lines 5-6), and an encoded electronic signature of the donor of the toxicology specimen in the vessel (Page 13, line 24 – page 14, line 1); and

a label imprinted with an identifying bar code attached to each vessel. (Figure 2, item 7).

18. A method for electronically storing data on a diagnostic or toxicology specimen vessel and remotely reading data from the vessel comprising:

at a vessel distribution facility (Figure 5, items 27, 28 & 31) providing a population of biomedical specimen vessels, each having a wireless electronic memory tag directly attached thereto, with data electronically stored on the electronic memory

tag including an electronic identification code stored on the electronic memory tag that is unique to the tag (Figure 4, item 11, page 12, line 19);

shipping members of the population having the electronic memory tags directly attached thereto with electronically stored data from the vessel distribution facility to a specimen collection facility (Figure 4, item 13); and

subsequently reading the stored data from the electronic memory tags with a non-contact electronic reader or scanner at a specimen testing laboratory facility (Figure 4, item 21).

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

at a vessel distribution facility (Figure 4, item 10) providing a population of biomedical specimen vessels, each having a wireless electronic memory tag directly attached to the vessel (Figure 4, item 11), with a unique electronic identification code stored on the electronic memory tag (Page 12, line 19);

distributing population members including the wireless electronic memory tag directly attached thereto to ~~a~~ specimen collection facilities (Figure 4, item 13);

collecting a specimen from a donor in the specimen vessel at one of the specimen collection facilities (Figure 4, item 14); and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag at the specimen collection facility at which the specimen is collected. (Page 11, lines 2-7).

20. A method as claimed in claim 19 further including collecting and storing an electronic signature of the specimen donor on the electronic memory tag at the

specimen collection facility at which the specimen is collected. (page 13, line 24 to page 14, line 2)

21. A method as claimed in claim 19 further including transporting the member vessel with collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical tests performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory. (page 11, lines 2-7)

38. A toxicology specimen system (Page 2, lines 16-17) comprising

a collection vessel (Figure 1) configured to receive and contain a toxicology specimen (Page 2, lines 16-17),

a tamper-indicating seal, (Page 11, lines 10-12) and

wireless electronic memory tag directly attached to the vessel such that the tag remains directly attached to the vessel as the vessel is transported (Figure 1, item 3, page 12, line 19), the tag providing non-contact storage and retrieval of information and wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen (Page 13, line 24 – page 14, line 1) and a unique electronic identification code stored on the electronic memory tag.

42. A toxicology specimen system (Page 2, lines 16-17) comprising

a population of collection vessels (Figure 4, item 10),

each member of the population of collection vessels configured to receive and contain a toxicology specimen and having a wireless electronic memory tag directly attached to the vessel for non-contact storage and retrieval of information (Page 11,

lines 13-21), the memory tag containing a unique electronic identification code stored on the electronic memory tag (Page 12, line 19) and stored data including an encoded electronic signature of the donor of a toxicology specimen (Page 13, line 24 – Page 14, line 1),

wherein the population includes a member at a specimen collection facility, and a member at a specimen testing laboratory facility and

wherein the members are transportable between the facilities and the tag is directly attached to the vessel such that it remains directly attached to the vessel at the facilities and as the vessel is transported between facilities (Figure 5, items 27, 28 & 31).

43. A toxicology specimen system (Page 2, lines 16-17) comprising:

a biomedical specimen collection vessel and a tamper-indicating, wireless electronic memory tag (Page 11, lines 10-12) having a unique electronic identification code stored on the electronic memory tag, the tag being directly attached to the vessel such that the tag remains directly attached to the vessel as the vessel is shipped to and among a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility (Figure 5, items 27, 28 & 31), the tag including a radio frequency transponder for non-contact storage and retrieval of information (Page 11, lines 13-21);

data stored on the electronic memory tag including an identification code for the vessel (Figure 4, item 11), the identity of the supplier of the vessel (Page 11, line 2) and product information about the vessel (Page 11, line 2), the tag configured to receive identifying information about a specimen contained in the vessel and about

the specimen donor (Page 11, lines 4-5), definition of the analytical tests to be performed on the specimen in the vessel (Page 11, lines 5-6), and an encoded electronic signature of the donor of the toxicology specimen in the vessel (Page 13, line 24 – Page 14, line 1); and

a label imprinted with an identifying bar code (Figure 2, item 7).

44. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel (Page 2, lines 16-17) comprising:

providing a population of biomedical specimen vessels, each of the specimen vessels having a wireless electronic memory tag directly attached to the specimen vessel, wherein the population includes a member at a vessel distribution facility (Figure 4, item 10), a member at a specimen collection facility (Figure 5, item 28), and a member at a specimen testing laboratory facility (Figure 5, item 31), and wherein each of the vessels includes a wireless electronic memory tag with a unique electronic identification code stored on the electronic memory tag (Figure 3, page 12, line 19) directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel (Figure 1, item 3) is transported between facilities;

collecting a specimen from a donor in a specimen vessel at the specimen collection facility (Figure 4, item 14);

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag (Page 11, lines 2-7)

attached to the vessel into which the specimen is collected at the facility (Page 13, line 24 – page 14, line 1) including

the electronic signature of the specimen donor.

45. A diagnostic specimen system as claimed in claim 1 wherein the specimen collection facility is selected from the group consisting of hospitals, clinics, doctors' offices and combinations thereof. (page 12, line 24 to page 13, line 1)

46. A diagnostic specimen system as claimed in claim 1 wherein the specimen collection facility and specimen testing laboratory facility are remote from one another so that members of the population at the specimen collection facility being transported to the specimen testing laboratory facility are couriered from the specimen collection facility to the specimen testing laboratory facility. (page 14, lines 13-16)

47. A diagnostic specimen system as claimed in claim 1 wherein the specimen collection facility and specimen testing laboratory facility are remote from one another so that members of the population at the specimen collection facility being transported to the specimen testing laboratory facility travel in a shipping carton. (page 14, line 20)

48. A diagnostic specimen system as claimed in claim 1 wherein none of the members of the population located at the vessel distribution facility contain specimens (page 12, lines 17-18)and some of the members of the population located at the specimen collection facility and specimen testing laboratory facility contain specimens. (page 13, lines 1-6)

49. A population of biomedical specimen collection vessels comprising

population members located at a vessel distribution facility (Figure 5, item 27),

population members located at a specimen collection facility (Figure 5, item 28), and

population members located at a specimen testing laboratory facility (Figure 5, item 31),

wherein each vessel of the population has a wireless electronic memory tag directly attached to the vessel, the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information (Figure 1, item 3),

wherein data stored on the electronic memory tags of all of the population members includes a unique identification code for the vessel (Page 12, line 19),

wherein data stored on the electronic memory tags of the population members located at the specimen collection facility and specimen testing laboratory facility includes identifying information about a specimen contained in the vessel (Page 11, lines 4-5) and about the specimen donor (Page 11, lines 4-5), and an encoded electronic signature of the donor of the toxicology specimen in the vessel (page 13, line 24 – Page 14, line 1), but the data stored on the electronic memory tags of the population members located at the vessel distribution facility does not include identifying information about a specimen contained in the vessel, nor information about the specimen

donor, nor an encoded electronic signature of the donor of the toxicology specimen in the vessel.

6. Grounds of Rejection to be Reviewed on Appeal

The following rejections are appealed:

A. Whether Claims 1-17, 38, 40-43 and 45-49 are indefinite under 35 U.S.C. 112, second paragraph.

B. Whether Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-48 are anticipated by U.S. Patent No. 6,535,129 to Petrick ("Petrick") under 35 U.S.C. 102(b).

C. Whether Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 45-48 are anticipated under 35 U.S.C. 102(b) by U.S. Patent No. 5,777,303 to Berney ("Berney").

D. Whether Claim 18 is unpatentable under 35 U.S.C 103(a) over Petrick or Berney.

E. Whether Claim 21 is unpatentable under 35 U.S.C. 103(a) over Berney.

F. Whether Claims 5, 8, and 13 are unpatentable under 35 U.S.C. 103(a) over Petrick or Berney in view of U.S. Patent No. 5,314,421 to Leuenberger ("Leuenberger").

G. Whether Claims 16-17, 20, 42-44, and 49 are unpatentable under 35 U.S.C. 103(a) over Petrick or Berney in view of U.S. Patent No. 5,613,012 to Hoffman et al. ("Hoffman") or U.S. Patent No. 5,948,103 to Fukuzaki ("Fukuzaki").

H. Whether Claims 2 and 10 are unpatentable under 35 U.S.C. 103(a) over Berney in view of disclosure of RD 421048 A ("RD 421048 A").

I. Whether Claims 3-4 and 11-12 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, and further in view of EP 1,004,359 A2 to Stevens et al. ("Stevens").

J. Whether Claim 38 is unpatentable under 35 U.S.C. 103(a) over Berney in view of U.S. Patent No. 5,135,313 to Bowman ("Bowman").

K. Whether Claim 8 is unpatentable under 35 U.S.C. 103(a) over Berney, in view of RD 421048 A, Stevens and Leuenberger.

L. Whether Claim 17 is unpatentable under 35 U.S.C. 103(a) over Berney, in view of RD 421048 A, Stevens, Leuenberger and Hoffman or Fukuzaki.

7. Arguments

A. Claims 1-21 and 40-44 Are Not Indefinite.

The Examiner rejected Claims 1-21 and 40-44 as indefinite, incorrectly asserting that they may not be directed to statutory subject matter.[1] The Examiner also rejected Appellant's claims as indefinite, asserting that certain of Appellant's claim limitations do not recite a particular structure, and so, do not limit the scope of its claims.[2] Then, the Examiner concluded that, since some of Appellant's claim limitations are not directed to specimen collection vessels, those limitations rendered claims to a larger specimen system indefinite, so the Examiner disregarded the limitations.

As to the rejection of claims under 35 USC Section 112, second paragraph, the Examiner is conflating the standards of Section 112, second paragraph and section 101. Section 112, second paragraph only requires that the claims have enough clarity so that those of ordinary skill in the art can understand the metes and bounds. There is no doubt that the claims are clear enough so that one of ordinary skill in the art can understand those metes and bounds.

As the Supreme Court has recognized, Congress chose the expansive language of 35 U.S.C. 101 so as to include "anything under the sun that is made by man" as

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[1] Paragraph 8 of Office Action mailed July 13, 2010. ("According to 35 U.S.C. 101, patentable inventions are related to 'any new and useful process, machine, manufacture, or composition'. It is not clear, which category of this four the claimed subject matter belongs to.").

[2] Id. ("*Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a* ***particular structure*** *does not limit the scope of a claim or claim limitation.*").

statutory subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980).

The four categories of subject matter eligible for protection are meant to capture anything under the sun made by man.[3] Accordingly, a "manufacture" has been described as any man made item not found in substantially the same form in nature that is neither a machine nor a composition of matter.[4] Certainly, a population of biomedical specimen collection vessels, at least some members of the population being located at vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility and additional members of the population being transported between the facilities falls within that expansive definition. What is claimed is a population, with further the limitations that members of the population are located at the recited locations, not the locations themselves.

The Examiner concedes that the vessels are a manufacture, but apparently claiming them as being in different facilities and taking into account their movement between the facilities causes confusion in the Examiner's mind and makes their status as manufactures suspect. Even if the claims are construed to cover a situation that may exist only momentarily, it will exist. A series of specimen collection vessels starting at the vessel distribution facility and working their way to the specimen collection facility and laboratory facility will, at least temporarily, be in the positions claimed. The fact that the claims cover a situation that may not be permanent as to a

[3] *Diamond v. Chakrabarty* 447 U.S. 303, 309, 206 USPQ 193, 197 (1980).

[4] 1 DONALD S. CHISUM, *Chisum on Patents* § 1.02[3] (2006) discussing 1 W. Robinson, *The Law of Patents for Useful Inventions* 270 (1890).

particular set of vessels does not make them indefinite. See *In re Hruby*, 373 F.2d 997, 153 USPQ 61 (CCPA 1967) holding that the pattern of water made in a water fountain is a manufacture, despite the fact that the water is in movement and does not statically remain as depicted.

The Examiner wonders about the changing status of the vessels, but that is not proper. Even a short-lived state of affairs – like the pattern of a water fountain, suffices. Other, indisputable articles of manufacture, (let's say an iPhone 4), has a finite life (let's say 10 years to be conservative) from the perspective of a 13.7 billion year old universe, ten years is quite transient. We hypothesize that if that life of ten years shrinks to ten milliseconds, the iPhone would not cease to be an article of manufacture.

The Examiner concludes (top of page 3 of the July 13, 2010 office action) that the location recitations should be given no weight in the article of manufacture claims, without citing authority for her position. Appellant believes the location definitions are to be given weight, but even if they were not given weight, the result would simply be very broad claims to manufactures, still statutory and still definite. Appellant may claim a manufacture under 35 U.S.C. 101, and further specifying locations that may be temporary does not render such claims non-statutory or indefinite.

Patent claims frequently recite elements in various positions, and those positions are attributes of the elements that are given weight in the evaluation of patentability. Literally thousands of issued U.S. patents employ the term "located at" or some very similar variation thereof in their claims to describe the subject matter

protected. Attached as Exhibit A are claims from 18 patents where the location of an article of manufacture or component thereof is mentioned in a claim. Did the Patent and Trademark Office mistakenly issue all of these patents?

The Examiner went on to observe that "the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.'' If the claims are read in light of appellant's disclosure, that construction is unreasonably broad. Moreover, appellant's claims 1-17, 21, 40-41 mention transporting the vessels between the claimed facilities, and the word "transporting" negates this interpretation. It would be a very unusual way to use the English language to say "I am transporting this vessel from a shelf in the laboratory two feet to the work bench," or the like. In particular, Claim 18 uses the term "shipping," hardly an intra-lab movement. Claims 45-47 add recitations that reinforce this "not all in one lab" connotation.

The Examiner cites no authority for her finding that the recitation of a population of vessels at the locations enumerated in Appellant's claims is to be given no weight, and indeed, counsel has found none in his research. Nor is there precedent for the analysis that one ignores words of claims in a section 112 evaluation if, by themselves, they would not constitute patentable subject matter under section 101. The dissection of a claim to pick and choose elements that may or may not be statutory subject matter has long been eschewed. *In re Deutsch*, 553 F.2d 689, 693, 193 U.S.P.Q. 645 (CCPA 1977).

Instead of being language to be ignored, recitations of the location of elements can be a critical element in determining patentability under section 103. For example,

as is well known, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) In *Gordon*, the claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were **located** at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. This Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The Court of Appeals reversed, finding that if the prior art device was turned upside down, it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged. MPEP 2143.01 Hence, whether the inlets were **located** at the top or the bottom was critically important.

In fact, claims have been held invalid for NOT reciting a location. If the specification discloses that a particular location is critical or essential to the practice of the invention, failure to recite or include that particular location in the claims may provide a basis for a rejection based on the ground that those claims are not supported

by an enabling disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In *Mayhew*, the examiner argued that the only mode of operation of the process disclosed in the specification involved the use of a cooling zone at a particular location in the processing cycle. The claims were rejected because they failed to specify either a cooling step or the **location** of the step in the process. The court was convinced that the cooling bath and its **location** were essential, and held that claims which failed to recite the use of a cooling zone, specifically located, were not supported by an enabling disclosure. MPEP 2174.

Similarly, in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) claims to a sectional sofa comprising, inter alia, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened during prosecution by removing the limitation defining the **location** of the control means.

Definiteness of claim language under 35 U.S.C. 112 is analyzed in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one of ordinary skill in the art at the time of the invention.[5] Potential infringers need to be apprised of the scope of patent protection defined by a patent's claims, and they would have no problem with Appellant's claims in that regard.

Figure 5 of Appellant's application illustrates, schematically, a specimen container supplier, a specimen collection site, and a laboratory. One of ordinary skill would understand that Appellant claims a system that includes a population of

[5] MPEP 2173.02.

vessels, members of which are at specified facilities and transported between the facilities. Appellant's claims are not indefinite for failing to describe statutory subject matter. Nor are Appellant's claims indefinite for claiming data, or for limiting claim elements to specified locations. Therefore, the Examiner's rejections of Claims 1-20 and 40-44 as indefinite should be reversed.

To the extent the examiner's position is based upon the vessels at the vessel distribution facility, specimen collection facility and specimen testing facility not being structurally different from each other, such analysis is in error. The wireless electronic memory tags on the vessels each have a unique electronic identification code stored on them. Each vessel is unique-not all the same as the examiner postulates. The code is electronic; it is not a mere writing to be disregarded. Her position that the vessels are identical is particularly inapt when it comes to claims 19 – 21 and 44 and claims 48 and 49. Claim 48 specifically adds structural distinctions between the members of the population located at the vessel distribution facility (they contain no specimen) and members of the population located at the specimen collection facility and specimen testing laboratory facility, which contain specimens. Similarly, in claims 19-21, 44 and 49 the vessels are differentiated from each other by the electronic data that is stored on their respective electronic memory tags.

B. Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 44 Are Not Anticipated by Petrick.

The Patent Office accorded Appellant a filing date of December 14, 2000 for the application that is the subject of this Appeal. After several official exchanges

between the Examiner and Appellant, an Office Action mailed January 15, 2004, rejected claims of the application for the first time under 35 U.S.C. 102(e) over U.S. Patent 6,535,129 to Petrick, which issued March 18, 2003 on an application filed November 17, 2000. Appellant submitted Rule 1.131 declarations of co-inventors Jason Bowman, Danny Charles Bowman and David Michael Lewis showing invention of the claimed subject matter antedating the filing date of Petrick to remove the reference as prior art.[6]

The examiner found no fault in the proof that Appellant antedates Petrick. Instead, she "indicate[d] that [Appellant's and Petrick's] inventions are not patentably distinct, so that 37 CFR 1.131 is not available to Appellants.

Petrick discloses a chain of custody form that has a radio frequency identification chip built into the form in order to establish a chain of custody that Petrick points out as being very important. As seen in Petrick's Figure 3b, the form is a conventional business form, allowing data to be entered by pen or pencil, with a tear strip on the right side encapsulating the RFID chip. Figure 3A has the RFID chip in the top of the form. The person taking the sample from the donor fills out the form and tears the RFID chip off the form to paste it to the collection container. That enables the data in the RFID chip to travel attached to the container to the laboratory. The RFID chip starts out being attached to the business form, not a collection container. The paper connection is the foundation of Petrick's chain of custody

[6] Appellant first responded June 15, 2004 to the Office Action mailed January 15, 2004. The Patent Office then issued a Notice of Non-Compliant Amendment July 6, 2004, to which Appellant responded July 9, 2004. Appellant later also submitted a Supplemental Response to the June 15, 2004 Office Action on July 23, 2004. The declarations swearing behind Petrick are contained in these three submissions following the June 15, 2004 Office Action.

proof. Of importance to Petrick is the fact that the tearing of the chip from the form causes at least partial destruction of the form to provide visual evidence of the correlation of the chip with the form, so that the data on the form becomes linked to the RFID chip. (See column 3, lines 43-46). Petrick says nothing about a vessel distribution facility, or members of a population of vessels located there. Figure 1 shows that the use of the form starts with the collection custodian (comparable to appellant's "specimen collection facility"). She tears the RFID chip off of the form and uses it to seal the container holding the specimen. (See column 3, lines 38-55) She also enters data into the business form.

The Petrick specification at column 3, lines 17-20 indicates that an RFID chip may be associated with the container 100 or the form 102. However, the claims of Petrick do not read on the RFID chip being associated with the container to start with. Instead, they are limited to the RFID chip being a part of the business form so that "de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form." See claim 8 of Petrick, column 6, lines 32-34.

Johnson & Johnston Associates v. R.E. Service Co., 285 F.3d 1046 (Fed.Cir.2002) (en banc), held that a patent applicaant who discloses but does not claim subject matter has dedicated that matter to the public and cannot reclaim the disclosed matter under the doctrine of equivalents. Thus, the claims of the Petrick patent cannot be construed to read on an embodiment in which an RFID chip starts out affixed to the container before it gets to the collection custodian, but must be

limited to an RFID chip that is part of the business form from which it must be removed – leaving destruction as evidence.

MPEP §715.05 incorporates 37 CFR 41.203(a) to define "same patentable invention," which states the general rule for determining whether an application is claiming the same patentable invention as a patent thusly:

> *Interfering subject matter*. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing part and vice versa.

In the first step of the analysis, the claimed invention of Petrick is presumed to be prior art to the Appellant. If Appellant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the second step is undertaken in which Appellant's claim is presumed to be prior art to Petrick's, and the reverse analysis is performed. If Petrick's claim is new and non-obvious in view of Appellant's claim, the claims describe separate patentable inventions. The claims describe the same patentable inventions only if Petrick's claimed invention anticipates or renders obvious Appellant's claimed invention *and* vice versa. The analysis refers only to the parties' claims, not the remainder of the specifications. In this case neither party's claims anticipate or make obvious the claims of the other party.

B.1. Evaluation of Appellant's System Claims 1-17 and 40-43

Petrick's Claims 1 and 7 read:

> 1. A business form comprising:
>
> a first portion providing chain of custody information therein; and
>
> a second portion linking said form with at least one specimen;
>
> wherein said business form further includes a wireless identification device associated therewith that electronically provides at least an identifier in response to a query for automatically establishing the chain of custody of said specimen, said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form.
>
> 7. The business form of Claim 1 wherein said wireless identification device is adhered directly to the specimen or to a container containing the specimen.

And Appellant's Claim 1 states:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels, at least some members of the population being located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members of the population being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag, a unique electronic identification code stored on the electronic memory tag for non-contact storage and retrieval of information directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities.

Thus, Petrick's claim requires the *wireless identification device to be associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form*, necessarily implying some physical connection of the form to the wireless identification device. Petrick does not claim any vessels with identification devices at a vessel distribution facility. Appellant's claims, on the other

hand, all have a requirement that the population of specimen collection vessels having a wireless electronic memory tag directly attached to the vessel include members at the vessel distribution facility. Furthermore, Appellant's claims do not mention a business form at all, much less first and second portions of a form, the disassociation of which results in visible partial destruction.

In the July 13, 2010, office action page 17-18, the examiner quotes page 11 of Appellant's specification that discusses a label 4 for the vessel, and she concludes that the label is the same as Petrick's business form. Her conclusion is erroneous. Appellant does not disclose, and certainly does not claim, destruction of the label to de-associate the device from the form, as required by Petrick's claim. Nor would it make sense to tear the chip of off Appellant's vessel, since that destroys the intended functionality. In fact, Appellant's claims says the memory tag is directly attached to the vessel in a way so that it remains attached at the facilities and as the vessel is transported. Again, the examiner's analysis does not limit the comparison of what Appellant claims to what Petrick claims.

***B.1.(a) Assuming Petrick is Prior Art to Appellant for* 41.203(a)Test**

Assuming Petrick's claim is prior art, Appellant's claim is novel. Appellant's claim describes a diagnostic specimen system including a population of collection vessels having members at specified locations. Petrick's claim does not disclose multiple vessels at the specified locations. Appellant's claim is therefore new in view of Petrick's claimed invention.

Appellant's diagnostic specimen system is also not an obvious variation of Petrick's business form. Nothing in Petrick's claim teaches or suggests the vessels at various locations set forth in Appellant's claim, particularly not the vessels at a vessel distribution facility and bearing the memory tag. Petrick puts the tag on the container at the specimen collection facility, after the specimen has been collected in the container (Column 3, lines 6-16).

Appellant's claim is not directed to the same subject matter. Petrick claims a business form; Appellant claims a system comprising a population of vessels. Petrick's wireless identification device (WID) is attached to the form in her claim 1--not the specimen collection vessel. Petrick's Figure 3B embodiment discussed at column 5, lines 19-36 (and her claim 7) suggests removing the wireless identification device from the form as part of a label used to seal the vessel shut. But, that still completely omits (and contra-indicates!) vessels with the tags at the vessel distribution facility, since Petrick's seal and RFID chip can not be added until the specimen has been collected in order to be consistent with Petrick's column 3, lines 38-56. Petrick emphasizes the importance of keeping the tag with the form, (at least until conspicuous removal takes place), so it would not have been obvious to put the tag on the vessel at the vessel distribution facility. Therefore, Appellant is not claiming the same patentable invention as Petrick's Claim 1 or 7, since doing so would negate what Petrick takes pains to make happen.

***B.1.(b) Assuming Appellant Is Prior Art to Petrick for* 41.203(a) Test**

If Appellant's claim is assumed to be prior art to Petrick's, the same result obtains. Petrick's claim 1 requires a new business form having two portions and a particular association between the business form and the wireless identification device. Appellant's claim does not disclose or suggest a business form (much less one having two portions) or any particular relationship between such a form and an identification device. The Examiner apparently contends that Appellant's bar code 7 (see office action of July 13, 2009, page 17) is a business form. Such a label is far from a business form as claimed by Petrick, which requires that the "*wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form.*" Appellant's claims do not mention or give a reason for any of that. Thus, Petrick's claim is non-obvious in view of Appellant's claim.

None of Petrick's other "business form" claims 2-6 add recitations that change this analysis. Nor do Appellants other apparatus claims 2-17, 38, 40-43, 45-49 claim the same apparatuses as Petrick. None of them claim the conspicuously dissassociateble form and claims 2-17, 40, 41, 43-49 require vessels with memory tags at the vessel distribution facility. Claims 38 and 42 require storage of an electronic signature, and Petrick does not claim a tag with an electronic signature.

B.2. Evaluation of Appellant's Method Claims 18-21 and 44

Petrick's Claim 8 recites:

A method of establishing a chain of custody comprising:

associating a business form and a radio frequency identification device with at least one object, said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form; and

using both the business form and the radio frequency identification device in combination to establish a chain of custody for the object including querying said device and receiving a response that is automatically used to establish said chain of custody.

And Appellant's Claim 18 reads:

18. A method for electronically storing data on a diagnostic or toxicology specimen vessel and remotely reading data from the vessel comprising:

at a vessel distribution facility

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag directly attached thereto, with data electronically

stored on the electronic memory tag including an electronic identification code stored on the electronic memory tag that is unique to the tag;

shipping members of the population having the electronic memory tags directly attached thereto with electronically stored data from the vessel distribution facility to a specimen collection facility; and

subsequently reading the stored data from the electronic memory tags with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

***B.2.(a) Assuming Petrick Is Prior Art to Appellant for* 41.203(a)Test**

The Examiner asserts that Appellant's Claim 18 and Petrick's Claim 8 claim the same patentable invention, but Petrick's claim does not teach or suggest Appellant's providing claimed biomedical specimen collection vessels at its claimed facilities, or storing data on a tag on a vessel at a vessel distribution facility. Nor does Petrick's claim recite collecting a specimen from a donor as does Appellant's Claim 19, or collecting and storing an electronic signature, as do Appellant's Claim 20 and 44. Appellant's claims 19 – 21 and 44 also require vessels at the vessel distribution facility bearing tags already having a code. So, Appellant's Claims 18-21 and 44 are both new and non-obvious in view of Petrick's Claim 8. Petrick's claim 8 and dependents thereon do not teach or suggest that memory tags be on the vessels and

bearing stored data at a vessel distribution facility. Petrick's discussion of its Fig. 3B teaches away from putting data on the tag of the specimen vessel at a vessel distribution facility, since adhering the seal to enclose an already-collected specimen in Petrick is the action that applies the RFID tag. This step is how Petrick provides the chain of custody claimed in claim 8 (see column 3, lines 38-49), so it cannot be omitted. So, Appellant's Claims 18-21 and 44 are new and non-obvious in view of Petrick's Claim 8. Petrick's dependent method claims 9-16 do not change the analysis.

***B.2.(b) Assuming Appellant Is Prior Art to Petrick for* 41.203(a)Test**

None of Appellant's method claims 18-21 or 44 teach or suggest the business form or Petrick's claimed particular association between Petrick's business form and its wireless identification device *"associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form."* Appellant's claims do not disclose or give a reason to use such a business form. So, Petrick's Claim 8 and claims dependent on claim 8 are new and non-obvious from Appellant's method claims, and Appellant is not claiming the same patentable invention as the Petrick patent.

The Examiner insists that Appellant and Petrick claim the same patentable invention without showing that Petrick's claims anticipate or render Appellant's claims obvious. She repeatedly wholesale imports the parties' specifications and derives implications from the specifications in making her analysis. She is required

to limit her analysis to the claims. As this Board stated in *USV Limited, B.S.D. v State of Oregon*, Appeal Number 2009-005002, 2009 WL 2807855 at page 23 (BPAI 2009):

> Here, the Examiner has failed to provide any meaningful two-way analysis that the subject matter of the Penhasi claims is directed to the same patentable invention as the claims of the 005 patent. For example, the Examiner contends that the Penhasi claims "encompass" particular limitations of the 005 patent claims as indicated by preferred ranges disclosed, but not claimed, by Penhasi. However, it is the claims of Penhasi, not preferred embodiments or preferred ranges disclosed in its specification, that are the assumed prior art for purposes of determining whether two parties are claiming the same subject matter.

Appellant is not claiming the same patentable invention as Petrick. Appellant can properly swear behind Petrick, so the rejections of Appellant's claims using Petrick as prior art should be reversed.

B.4. Responding to the Examiner's Comments

Appellant's claim 1 recites a population of biomedical specimen collection vessels, at least some members of the population being located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members being transported between the facilities. Petrick's claims 1 and/or 7 do not have members of populations of vessels at these various facilities, particularly members at the vessel distribution facility and having the wireless tag directly attached. The Examiner asserts that the location of the claimed vessels does not bear patentable weight. As pointed out above, the examiner

is wrong in that respect, and that may contribute to her error concerning whether or not Appellant and Petrick are claiming the same patentable invention.

On page 16 of the July 10, 2010 office action, the Examiner apparently tries to comply with the two-way test for determining whether Appellant and Petrick are claiming the same patentable invention, but she is unsuccessful. The Examiner quotes a passage from Appellant's specification, page 11. The passage that the Examiner refers to says electronic memory tag 3 can include a carrier label 4 which has a front face 5 and a rear face 6, with an identification bar code 7 on the front face. A text area can also be provided for printing, typing or writing pertinent information on the front face carrier label 4.

The Examiner's position is that this specification disclosure defines Appellant's claim to the point of causing the claim to read on that embodiment and that the subject matter disclosed in connection with Figure 2 is the same as what Petrick claims with respect to its business form. However, Petrick's business form as claimed in ALL of Petrick's claims includes two portions and a wireless identification device that is associated with a form, such that the associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through a visual inspection of the form. Nothing in the passage of Appellant's specification cited by the Examiner teaches or suggests de-associating the device from the form resulting in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form. The readily discernable partial destruction is a concept that is core to Petrick's claims, but totally absent from Appellant's claims (and specification for that matter). Thus, Appellant's claims

cannot make Petrick's claim obvious, so different patentable inventions are being claimed, and the 1.131 declaration is to be given effect.

Later on page 16, she points out that Petrick's claim 8 recites establishing a chain of custody. From there she bootstraps that a chain of custody for a biological specimen inherently comprises distributing, transferring, and analyzing the specimen in the containers. Petrick's claim 8 does not mention any of that --- not even "biology." The phrase "chain of custody" does not necessarily imply the examiner's phrase which is "distributing, transferring and analyzing specimen in the container at the corresponding locations," nor the specificity of Appellant's claims.

Petrick emphasizes the association of the RFID chip with the form by the fact that the chip's disassociation from the form is to be evident. This relationship of the chip to the form is fundamental to Petrick's chain of custody scheme and is a material limitation in her claims. But this fundamental relationship teaches away from Appellant's invention, in which the tag is applied to the vessel before it gets to the "collection custodian," and no form is mentioned. Thus, Appellant's claimed invention could not have been obvious from Petrick's claimed invention. The parties are claiming different inventions.

C. Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 45-48 Are Not Anticipated by Berney.

C.1. Claims 1, 6-7, 9, 14-15, 21, and 40-41 Are Not Anticipated by Berney.

Berney discloses a system for registering useful information during analyses of blood in conventional glass test tubes 1.[7] Berney's electronic memory labels 4 are attached to supports 31 that are fixed on the test tubes 1[8] in a testing laboratory at the time of sample analysis.[9] The supports 31 have a spring-like shape for attaching the test tubes[10] and rest on a base 33 including a bus system 46 for transferring information to and from the labels 4 during analysis.[11]

Berney does not disclose and is not concerned with vessels at a vessel distribution facility or a specimen collection facility. Berney's spring-like supports 31 tell one of ordinary skill in the art that the affixation to a test tube is temporary. At column 2, lines 29-30, Berney's statement that these allow a firm fixation of the label 30 onto the test tube 32 at the time of analysis clearly suggest that affixation at that time is the only time of concern to Berney. In particular, a spring-loaded mount which is obviously removable and re-useable, does not suggest a chain of custody proof system.

Berney's abstract says the label is attached to the test tube with a detachable support, confirming the notion that the attachment is temporary, not the sort of affixation used to accompany a specimen collection vessel transported from a distribution facility to a collection site and then to a lab, particularly if a secure chain

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[7] Col. 1, Line 11 of Berney.

[8] Col. 2, Lines 22-24 of Berney.

[9] Col. 1, Line 18; Col 1, Line 36; Col. 1, Lines 64-65; Col. 2, Line 29; Col. 3, Lines 18-25; Col. 4, Line 7 of Berney (Emphasis added).

[10] Col. 2, Lines 28-30 of Berney.

[11] Col 2, Lines 34-56, Figs. 3 and 4 of Berney.

of custody is important. There is no teaching or suggestion supporting the examiner's position that Berney discloses or suggests Appellant's invention.

Berney anticipates Appellant's claims only if each and every element as set forth in the claims is found either expressly or inherently described.[12] While she acknowledged that Berney does not expressly disclose Appellant's claimed inventions, the Examiner asserted that Berney inherently discloses Appellant's claimed population of biomedical specimen collection vessels. But, to be inherent, the features of Appellant's claimed invention must *necessarily* be present in the Berney disclosure, and Appellant's specified vessel locations are not even consistent with Berney's disclosure, much less, *necessarily present*. Berney's label provides a temporary mount to a test tube during analysis of the test tube contents in a laboratory; only one of the three facilities described by Appellant's claims. Thus, Berney does not inherently disclose any of Appellant's Claims 1, 6-7, 9, 14-15, 19, 21, 40-41, and 45-48. The Examiner's rejections of these claims should be reversed.

C.2. Claim 19 Is Not Anticipated by Berney.

Berney describes its process of performing an analysis thusly:

> [F]irstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central data base into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result

data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient.[13]

Thus, Berney's labels are attached in the lab and one of ordinary skill would appreciate that the labels are also removed in the lab, so that the labels can be reused with another test tube after the information is transferred from them to a centralized data bank. There is no reason to attach electronic labels to Berney's test tubes prior to sample collection because Berney says reference data of the patient is not transferred to the labels until during the time of sample analysis.[14] Thus, Berney is concerned with recording specimen analysis data, not complete chain of custody information, so Berney does not disclose electronic memory tags attached to vessels at a distribution facility, or distributing vessels having electronic memory tags to a collection facility. Therefore, Berney does not anticipate Appellant's Claim 19, and the Examiner's rejection of the claim should be reversed.

C.3. Claim 21 Is Patentable over Berney.

The Examiner rejected Claim 21 as anticipated by Berney, she also acknowledged that Berney does not disclose transporting vessels to a specimen-testing laboratory. But, she reasons, since transporting vessels is conventional medical practice, one of ordinary skill would have transported Berney's vessels, "because it allows tracking the vessels using Berney's inventive electronic tags on the specimen vessels." No, it does not. Berney does not put his clip-on identifier on the

[13] Col. 3, Lines 18-25.

test tube until the specimen is in the lab, so it could not be useful to track the specimen at the specimen collection facility.

In fact, Berney does not suggest distributing specimen collection vessels including wireless electronic memory tags to a specimen collection facility. Nor does Berney motivate one to do so. Berney is concerned with tracking information only at the lab - during the time of specimen analysis. The Examiner's rejection of Claim 21 as unpatentable over Berney should be reversed.

C.4. Claims 45-48 are patentable over Berney.

To the extent that the Examiner's interpretation of claim 1 as reading on various locations within the laboratory using Berney's invention, such an interpretation cannot be said to apply to the locations specified in claim 45 (specimen collection facility is a hospital, clinic, or doctor's office), or the remoteness of claim 46, or the shipping carton of claim 48. Further, Berney does not suggest clipping his temporary clip on an empty tube, as would be required for claim 48.

D. Claims 5, 8, and 13 Are Patentable Over Petrick or Berney in View of Leuenberger.

D.1.Claims 5 and 13 Are Patentable.

The Examiner concludes that it would have been obvious to store data including the identity of a specimen vessel and product information about the vessel on a memory tag. She said one of ordinary skill would modify Petrick to include such information 'because vessels (containers) from different suppliers may vary, and

therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).'[15]

Of course, Petrick is not prior art, but still, the reference fails to teach or suggest storing product information on an electronic memory tag attached to a specimen collection vessel. Petrick does not attach the RFID tag to the vessel until the sample is collected. Leuenberger says that paper labels have been used to store product information on blood packs, but that the paper labels exhibit certain disadvantages overcome by the use of microporous plastic film labels.[16] Thus, Leuenberger suggests paper or plastic film labels, but fails to suggest using an electronic memory tag to store product information. Berney discloses storing information on an electronic label in a laboratory during the time of specimen analysis. Neither Petrick, Berney or Leuenberger discloses storing product or manufacturer information on an electronic memory tag at a vessel distribution facility. Even if the Examiner were correct in asserting that product information "is always conventionally provided with all manufactured products," that fact says nothing about storing that information *on an electronic memory tag*, as Appellant claims. To say that one of ordinary skill would have combined Petrick or Berney with Leuenberger to produce an electronic memory tag having stored thereon manufacturer or product information bridges the gap between the references by using that which Appellant teaches against its teacher.

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[15] Paragraph 14 of Office Action mailed July 13, 2010.

[16] Col. 1, Lines 18-55 of Leuenberger.

Moreover, Petrick and Berney do not indicate that the maker of the vessel is of any concern. Petrick is all about business forms; indeed Petricks' wireless identification device starts out associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form. How and why one would research and record the collection vessel maker when using the Petrick business form is not at all clear from Petrick. Berney's applying his wireless device to the apparently reusable test tube certainly suggests that the original maker of the test tube is unimportant.

D.2. Claim 8 Is Patentable.

Claim 8 describes a diagnostic specimen system including a population of collection vessels each having attached thereto both an electronic memory tag and a label having an identifying bar code. Petrick is not prior art to Appellant's application and Berney discloses an electronic label for registering all useful information during the time of analyses of a specimen contained in a test tube. The reference does not teach or suggest a label having an identifying bar code attached to its test tubes. And, although Leuenberger discloses the use of microporous plastic film labels that may include an identifying bar code 16,[17] one of ordinary skill would find no suggestion or motivation to add Leuenberger's bar code to the test tubes disclosed by Berney because Berney's electronic label is provided for registering such information, so there is no use for a bar code. Therefore, Appellant's claim is

[17] Col. 2, Lines 5-55 of Leuenberger.

patentable in view of the references and the Examiner's rejection of Claim 8 should be reversed.

E. Claim 18 Is Patentable.

Petrick is not prior art to Appellant's application, and Berney does not disclose providing a population of biomedical specimen vessels that already store data on an electronic memory tag at a vessel distribution facility. Nor do the references disclose shipping members of a population of vessels that include electronic memory tags from a vessel distribution facility to a specimen collection facility. However one may move Berney's test tube around in his lab would not be "shipping" as claimed in claim 18. Thus, the references do not teach or suggest all of Appellant's claim limitations, so the Examiner's rejection of Claim 18 should be reversed. Note also that Petrick keeps the RFID tag with the paper form (see Figure 3B and the discussion at Column 5, lines 19-36) until the sample is collected and patient data is recorded on the form. Only then is the RFID chip pasted on the sample, not at a vessel distribution facility.

F. Claims 16, 17, 20, 42-44, and 49 are patentable over Petrick or Berney in View of Hoffman or Fukuzaki.

F.1. Claims 16, 42 and 43 Are Patentable

The Examiner asserted that one of ordinary skill would have combined the electronic signature disclosed in Hoffman or Fukuzaki with Petrick's or Berney's disclosure "specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of 'the person

under concern' is conventional in all diagnostic procedures."[18] Petrick, however, is not prior art to Appellant's application, and Berney does not disclose members of a population of specimen vessels at Appellant's claimed locations (particularly the vessel distribution facility positively recited in claim 43). Berney acknowledges no specimen collection from a donor, at all. Nor is there any apparent way to store an electronic signature of the donor of a toxicology specimen on Berney's test tubes, since the tags are attached during the time of sample analysis, not at the time of specimen collection. The office action cites column 1, line 68 of Berney as being relevant, but it has no mention of a signature.

Neither Hoffman nor Fukuzaki suggests including an encoded electronic signature of the donor of a toxicology specimen on an electronic memory tag. Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification in a commercial transaction system. Fukuzaki discloses an electronic document security system. Neither reference teaches or suggests a specimen vessel having a memory tag containing an encoded electronic signature.

F.2. Claim 17 is Patentable

The Examiner asserts that it would have been obvious to combine Hoffman or Fukuzaki with Petrick or Berney to produce Appellant's Claim 17.[19] Prior art references combined to establish obviousness, however, must yield all claim

[18] Paragraph 15 of Office Action mailed July 13, 2010.

[19] Paragraph 15 of Office Action mailed July 13, 2010.

limitations.[20] Appellant claims a toxicology specimen system including a population of specimen vessels having wireless electronic memory tags storing data including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel. Petrick is not prior art to Appellant's application but, even so, neither Petrick nor Berney teaches or suggests all the elements of Claim 17. Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither Hoffman nor Fukuzaki teaches or suggests a toxicology specimen system including a population of specimen vessels having wireless electronic memory tags storing data including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel. Therefore, Appellant's claim would not have been obvious to one of ordinary skill and the Examiner's rejection of the claim should be reversed.

F.3. Claim 20 is Patentable

Petrick is not prior art to Appellant's application, and neither Berney, Hoffman, nor Fukuzaki discloses a method that includes storing the electronic signature at the specimen collection facility. Therefore, Appellant's Claim 20 would not have been obvious to one of ordinary skill in the art and the Examiner's rejection of the claim should be reversed.

F.4. Claim 44 Is Patentable Over Berney in view of Hoffman or Fukuzaki.

Berney does not disclose collecting and storing the electronic signature of a specimen donor on an electronic memory tag at a specimen collection facility.

[20] MPEP 2143.

Berney does not even disclose collecting an electronic signature, much less collecting and storing one at a collection facility. The specimen donor, whose signature collection features in Claim 44, is not even present when Berney is using his clip-on test tube electronic label. Berney does not anticipate Appellant's Claim 44. And Berney is so different that regardless of what Hoffman or Fukuzaki may say about recording signatures, it would not have been obvious to do so in the context of Berney to perform the method of claim 44, so the Examiner's rejection of the claim should be withdrawn.

G. Claims 2 and 10 are Patentable over Berney in view of RD 421048 A.

To establish a *prima facie* case of obviousness, a combination of prior art references must provide a reason for one of ordinary skill in the art to reach the allegedly obvious claimed invention. Berney does not teach or suggest a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. RD 421048 A discloses a method for chemical management for tracking compounds within a chemical synthesis system including identification tags having passive transponders.[21] Modifying Berney to include RD 421048 A's passive transponders does not produce the diagnostic specimen system of Appellant's Claims 2 and 10 because RD421048 A does not disclose Appellant's claimed vessel locations. Thus, the subject matter of the claims would not have been obvious and the Examiner's rejections Berney in view of RD 421048A should be reversed.

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[21] ABSTRACT of RD 421048 A.

H. Claims 3-4 and 11-12 are Patentable over Berney in View of Stevens.

The Examiner asserts that it would have been obvious "to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to 'create a link between the container, the patient and the test request forms', or any other forms associated with using this container."[22]

Stevens discloses a sample collection tube 20 and a label 40 comprising a permanent portion 50 having a barcode 90 and a peel away portion 70 for affixation to a test request form or to another container or item.[23] Berney discloses an electronic label that provides for registration of *all* useful information required for analysis of a blood sample, however, and thus *eliminates* the need for jotting down and manual transfer of information.[24]

Therefore, Combining Stevens' barcode associated with a manual entry form with Berney's disclosure would destroy Berney's purpose of eliminating manual entry of information, so one of ordinary skill would not modify the references as proposed by the Examiner.[25] Even if one were to make such a modification, the result would still not produce Appellant's claimed vessel locations. Accordingly, the

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[22] Paragraph 17 of Office Action mailed July 13, 2010.

[23] Col. 5, Lines 25-27; Col. 6, Lines 19-21; Figure 8 of Stevens.

[24] Col. 1, Lines 30-32 of Berney.

[25] MPEP 2143.01(V.).

obviousness rejection of each of Claims 3-4 and 11-12 is improper and should be reversed.

On page 22 of the office action of July 13, 2010, the Examiner argues that Berney does not say all useful information should be written on the electronic tags. But, Berney says his goal is to "eliminating of the jotting down" at column 1, lines 31-32. If jotting is eliminated, there is no useful information left to jot.

I. Claim 38 is Patentable over Berney in View of Bowman.

The Examiner asserted it would have been obvious to modify Berney's specimen collection vessel by adding the tamper-indicating seal disclosed by Bowman "so that any attempted tampering with the specimen will be indicated by at least partial destruction of the seal."[26] Berney discloses electronic memory labels for registering all useful information during blood analyses, and Bowman discloses a chain-of-custody bag 10 for the sealing a specimen within the bag during transportation to an analysis site.[27] The references show no reason to modify Berney the way the Examiner hypothesizes. Berney is not concerned with transporting vessels from a collection facility to a laboratory; everything about Berney happens in the laboratory. There is no risk of tampering that needs evidencing. Berney's test tubes are provided with caps 2 that can be removed to permit access to a blood specimen;[28] so adding Bowman's seal to Berney's test tubes would interfere with

[26] Paragraph 18 of Office Action mailed July 13, 2010.

[27] Col. 3, Lines 9-19 of Bowman.

[28] Col. 1, Line 62, Fig. 1 of Berney.

removal of Berney's cap during specimen analysis. Therefore, the references would not have suggested such a modification,[29] and the Examiner's rejection of Claim 38 should be reversed.

If the Examiner's interpretation that the vessel distribution facility, specimen collection facility, and specimen testing laboratory facility are all within Berney's laboratory is accepted, there is still no reason to add a tamper-evident seal. Therefore, the references would not have suggested such a modification,[30] and the Examiner's rejection of Claim 38 should be reversed.

J. Claim 8 is Patentable over Berney in view of RD421048 A, Stevens and Leuenberger.

The Examiner further asserts that it would have been obvious to include product information on a thrice-modified version of Berney "because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the vessel."[31] Neither of these proffered motives, however, explains why one would have a reason to store supplier information *on an electronic memory tag*, as Appellant claims, rather than marking the product itself, as Leuenberger suggests. Thus, they fail to address the question whether one of ordinary skill would have had a reason to combine the references to produce the *claimed invention*. Arguments made above are also

[29] MPEP 2143.01(V.).

[30] MPEP 2143.01(V.).

[31] Paragraph 19 of Office Action mailed July 13, 2010.

applicable here. Therefore, the Examiner has failed to present a *prima facie* case of obviousness with respect to Claim 8, and the rejection of this claim should be reversed.

K. Claim 17 is Patentable over Berney in View of RD 421048 A, Stevens, Leuenberger and Hoffman or Fukuzaki.

The Examiner asserts that one of ordinary skill would have combined the encoded electronic signature of Hoffman or Fukuzaki with a thrice-modified version of Berney to produce Appellant's claimed invention that includes storing various items of information, including the specimen donor's signature.[32] Berney, however, discloses logging information concerning the person under concern only in a specimen analysis laboratory not the specimen collection facility where the donor may be asked to sign. Neither Hoffman nor Fukuzaki suggest storing a signature on an electronic memory tag. Also, Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither reference teaches or suggests a specimen vessel having a memory tag containing an encoded electronic signature. Therefore, the Examiner's rejection of Claim 17 should be reversed.

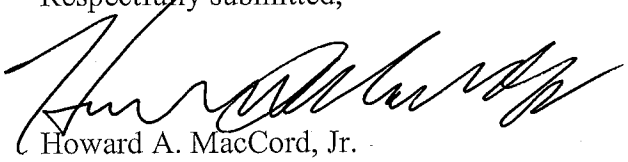
Conclusion:

The Examiner's rejection of the Claims should be reversed.

In conclusion, the rejections err in numerous ways, as outlined above. Fundamentally, the Examiner disregards the material recitations of the locations of

the various members of populations of vessels. Those are not arbitrary locations, but are there because of the progression of the members of the population from one location to the other during processing. At any point in time, some members will be at each location. Once the locations are given their proper weight, (and even if they are not) it is clear that Appellant and Petrick are not claiming the same invention, so that Appellant can successfully swear behind Petrick. Moreover, the Berney reference teaches only the use of a tag within a laboratory, and not among the various facilities of Appellant's invention. All of the rejections should be reversed and the claims allowed.

Respectfully submitted,



Howard A. MacCord, Jr.
Registration No. 28,639
MacCord Mason PLLC
P. O. Box 2974
Greensboro, NC 27402
(336) 273-4422

Date: November 29, 2010
File No.: 2552-011

[32] Paragraph 20 of Office Action mailed July 13, 2010.

8. Claims Appendix

The appealed claims are as follows:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels, at least some members of the population being located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members of the population being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag, a unique electronic identification code stored on the electronic memory tag for non-contact storage and retrieval of information directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities.

2. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag includes a radio frequency transponder.

3. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including an identification code for the vessel.

4. A diagnostic specimen system as claimed in claim 3 further including a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel.

5. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including the identity of a supplier of the vessel and product information about the vessel.

6. A diagnostic specimen system as claimed in claim 1 wherein electronic memory tags on vessels at the specimen collection facility contain stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

7. A diagnostic specimen system as claimed in claim 6 wherein an electronic memory tag on a vessel at the specimen collection facility contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

8. A diagnostic specimen system comprising:

a population of collection vessels, at least some members of the population being located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being

located at a specimen testing laboratory facility, and additional members being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag, with a unique electronic identification code stored on the electronic memory tag for non-contact storage and retrieval of information directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities;

data stored on electronic memory tags of members at the specimen collection facility including an identification code for the vessel to which the tag is directly attached, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, and definition of the analytical tests to be performed on the specimen in the vessel; and

a label imprinted with an identifying bar code attached to each vessel.

9. A toxicology specimen system comprising

a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag directly attached to the vessel for non-contact storage and retrieval of information,

wherein the population includes members located at a vessel distribution facility, other members of the population being located at a specimen collection

facility, further members of the population being located at a specimen testing laboratory, and additional members being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag, with a unique electronic identification code stored on the electronic memory tag for non-contact storage and retrieval of information directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities.

10. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag includes a radio frequency transponder.

11. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including an identification code for the vessel.

12. A toxicology specimen system as claimed in claim 11 further including a label imprinted with an identifying bar code attached to each vessel.

13. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including the identity of the supplier of the vessel and product information about the vessel.

14. A toxicology specimen system as claimed in claim 9 wherein electronic memory tags on vessels at the specimen collection facility contain stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

15. A toxicology specimen system as claimed in claim 14 wherein an electronic memory tag on a vessel at the specimen collection facility contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

16. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

17. A toxicology specimen system comprising:

a population of biomedical specimen collection vessels, wherein the population includes members located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members of the population being transported between the facilities,

each vessel having a wireless electronic memory tag directly attached to the vessel such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities, the electronic memory tag including a

radio frequency transponder for non-contact storage and retrieval of information; data stored on the electronic memory tags including an identification code for the vessel that is unique to the tag on the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and a label imprinted with an identifying bar code attached to each vessel.

18. A method for electronically storing data on a diagnostic or toxicology specimen vessel and remotely reading data from the vessel comprising:

at a vessel distribution facility providing a population of biomedical specimen vessels, each having a wireless electronic memory tag directly attached thereto, with data electronically stored on the electronic memory tag including an electronic identification code stored on the electronic memory tag that is unique to the tag;

shipping members of the population having the electronic memory tags directly attached thereto with electronically stored data from the vessel distribution facility to a specimen collection facility; and

subsequently reading the stored data from the electronic memory tags with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

at a vessel distribution facility providing a population of biomedical specimen vessels, each having a wireless electronic memory tag directly attached to the vessel, with a unique electronic identification code stored on the electronic memory tag;

distributing population members including the wireless electronic memory tag directly attached thereto to specimen collection facilities;

collecting a specimen from a donor in the specimen vessel at one of the specimen collection facilities; and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag at the specimen collection facility at which the specimen is collected.

20. A method as claimed in claim 19 further including collecting and storing an electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility at which the specimen is collected.

21. A method as claimed in claim 19 further including transporting the member vessel with collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical tests performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory.

22. – 37. **(Canceled)**.

38. A toxicology specimen system comprising

a collection vessel configured to receive and contain a toxicology specimen,

a tamper-indicating seal, and

wireless electronic memory tag directly attached to the vessel such that the tag remains directly attached to the vessel as the vessel is transported, the tag providing non-contact storage and retrieval of information and wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen and a unique electronic identification code stored on the electronic memory tag.

39. **(Canceled)**.

40. A diagnostic specimen system as claimed in claim 1 further including an electronic database accessible from the specimen collection facility for storing data entered at the collection facility.

41. A diagnostic specimen system as claimed in claim 40 further including an electronic network connecting the specimen collection facility to the specimen testing laboratory facility for transmitting data from the specimen collection facility to the specimen testing laboratory facility.

42. A toxicology specimen system comprising

a population of collection vessels,

each member of the population of collection vessels configured to receive and contain a toxicology specimen and having a wireless electronic memory tag directly attached to the vessel for non-contact storage and retrieval of information, the memory tag containing a unique electronic identification code stored on the electronic memory tag and stored data including an encoded electronic signature of the donor of a toxicology specimen,

wherein the population includes a member at a specimen collection facility and a member at a specimen testing laboratory facility and

wherein the members are transportable between the facilities and the tag is directly attached to the vessel such that it remains directly attached to the vessel at the facilities and as the vessel is transported between facilities.

43. A toxicology specimen system comprising:

a biomedical specimen collection vessel and a tamper-indicating, wireless electronic memory tag having a unique electronic identification code stored on the electronic memory tag, the tag being directly attached to the vessel such that the tag remains directly attached to the vessel as the vessel is shipped to and among a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, the tag including a radio frequency transponder for non-contact storage and retrieval of information;

data stored on the electronic memory tag including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, the tag configured to receive identifying information about a specimen

contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and

a label imprinted with an identifying bar code.

44. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each of the specimen vessels having a wireless electronic memory tag directly attached to the specimen vessel, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility, and wherein each of the vessels includes a wireless electronic memory tag with a unique electronic identification code stored on the electronic memory tag directly attached thereto such that the tag remains directly attached to the vessel at the facilities and as the vessel is transported between facilities;

collecting a specimen from a donor in a specimen vessel at the specimen collection facility;

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag attached to the vessel into which the specimen is collected at the specimen collection facility including

the electronic signature of the specimen donor.

45. A diagnostic specimen system as claimed in claim 1 wherein the specimen collection facility is selected from the group consisting of hospitals, clinics, doctors' offices and combinations thereof.

46. A diagnostic specimen system as claimed in claim 1 wherein the specimen collection facility and specimen testing laboratory facility are remote from one another so that members of the population at the specimen collection facility being transported to the specimen testing laboratory facility are couriered from the specimen collection facility to the specimen testing laboratory facility.

47. A diagnostic specimen system as claimed in claim 1 wherein the specimen collection facility and specimen testing laboratory facility are remote from one another so that members of the population at the specimen collection facility being transported to the specimen testing laboratory facility travel in a shipping carton.

48. A diagnostic specimen system as claimed in claim 1 wherein none of the members of the population located at the vessel distribution facility contain specimens and some of the members of the population located at the specimen collection facility and specimen testing laboratory facility contain specimens.

49. A population of biomedical specimen collection vessels comprising population members located at a vessel distribution facility,

population members located at a specimen collection facility, and

population members located at a specimen testing laboratory facility,

wherein each vessel of the population has a wireless electronic memory tag directly attached to the vessel, the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information.

wherein data stored on the electronic memory tags of all of the population members includes a unique identification code for the vessel,

wherein data stored on the electronic memory tags of the population members located at the specimen collection facility and specimen testing laboratory facility includes identifying information about a specimen contained in the vessel and about the specimen donor, and an encoded electronic signature of the donor of the toxicology specimen in the vessel, but the data stored on the electronic memory tags of the population members located at the vessel distribution facility does not include identifying information about a specimen contained in the vessel, nor information about the specimen donor, nor an encoded electronic signature of the donor of the toxicology specimen in the vessel.

9. Evidence Appendix

A. These references were cited by the Examiner in making rejections, and Appellant relies on portion of them to show the errors of the rejections. Copies are attached.

Patent Number or Document Number	1st Named Inventor	Examiner Cited in Office Action Dated
6,535,129	Petrick	13 July 2010
5,613,012	Hoffman	13 July 2010
5,777,303	Berney	13 July 2010
5,135,313	Bowman	13 July 2010
EP 1,004,359 A2	Stevens	13 July 2010
5,314,421	Leuenberger	13 July 2010
RD 421048 A		13 July 2010
5,948,103	Fukuzaki	13 July 2010

B. Additional evidence submitted by Appellant.

Declarations under Rule 1.131 of Jason Bowman, Danny Charles Bowman and David Michael Lewis, and Exhibits thereto. Copies are attached. Entered June 17, 2004.

Exhibit A: Claims from 18 patents reciting the location of an article of manufacture. Entered June 8, 2010.

10. Related Proceedings

This application was previously the subject of Appeal no. 2009-2011, which was remanded to the Examiner for further work on April 20, 2009. Appellant chose to reopen prosecution, but the examiner re-sent the case to the Board, where it was assigned Appeal number 2009-014382.

Appellant sought remand for consideration of arguments presented and Appeal number 2009-014382 was dismissed by a paper mailed January 26, 2010.